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| APPLICATION NO.                                                                               | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO.       |
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| 10/535,134                                                                                    | 01/17/2006  | Klaus Abraham-Fuchs  | 32860-000885/US         | 3591                   |
| 30596 7590 06/01/2007<br>HARNESS, DICKEY & PIERCE, P.L.C.<br>P.O.BOX 8910<br>RESTON, VA 20195 |             |                      | EXAMINER<br>SUN, XIUQIN |                        |
|                                                                                               |             |                      | ART UNIT<br>2863        | PAPER NUMBER           |
|                                                                                               |             |                      | MAIL DATE<br>06/01/2007 | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/535,134

Applicant(s)

ABRAHAM-FUCHS ET AL.

Examiner

Xiuqin Sun

Art Unit

2863

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8, 10-22 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (U.S. Pub. No. 20030004696) in view of Ertel (U. S. Pat. No. 5307262).

Regarding claim 1, Yamazaki et al. disclose a method for carrying out quality control for an analysis process including a chain of sub-processes, the method comprising: storing at least one of fundamental chemical and physical basic sub-processes for the group in a first database (sections 0030-0035 and 0040); representing at least a part of the chain of the analysis process by specifying one of the basic sub-processes, per sub-processes of the part of the chain, using at least one control parameter and at least one associated threshold value (sections 0043 and 0161); determining measurement values of the control parameters for at least one run of the analysis process (sections 0162 and 0163); comparing the measurement values with the associated threshold values for the quality control (sections 0162 and 0163);

and outputting a result of the comparing the measurement values with the associated threshold values for the quality control (section 0043).

Yamazaki et al. do not mention expressly: said comparison is in a chronological order of the occurrence of the sub-processes in the part of the chain in the course of the analysis process.

Ertel teaches a method for carrying out quality control for an analysis process including a chain of sub-processes (Abstract), including: comparing measurement values with associated threshold values for the quality control in a chronological order of the occurrence of the sub-processes in the part of the chain in the course of the analysis process (col. 5, lines 35-39; col. 11, lines 50-55; col. 15, lines 11-20; col. 26, lines 61-68; col. 30, lines 13-19; cols. 35-36, lines 50-8).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Yamazaki et al. by including the data comparison technique as taught by Ertel in order to in order to monitor the overall performance of the data quality control process and performance trends over time as well as conduct more detailed case-specific quality control surveillance (Ertel, Abstract and col. 35, lines 50-60).

Regarding claim 2, Yamazaki et al. disclose: wherein the analysis processes includes at least one of chemical and biochemical analysis process (section 0148).

Regarding claim 3, Yamazaki et al. disclose: wherein at least one of the basic processes is used repeatedly for the representation (sections 0112, 0219 and 0314).

Regarding claim 4, Yamazaki et al. disclose: wherein the part of the chain contains only the quality-relevant sub-processes (sections 0031-0036).

Regarding claim 5, Yamazaki et al. disclose: wherein representation is aided by a correspondingly designed graphical user interface.

Regarding claim 6, Yamazaki et al. disclose: wherein the graphical user interface aids the representation by at least one of drag-and-drop techniques, drop-down lists and checking list elements with a mouse click (section 0005).

Regarding claim 7, Yamazaki et al. disclose: wherein the represented part of the chain is stored with the control parameters and threshold values in a second database (sections 0045, 0049, 0051, 0054 and 0055).

Regarding claim 8, Yamazaki et al. disclose: wherein associated measurement values lying above or below the threshold values are evaluated during the comparison (sections 0162, 0163 and 0165).

Regarding claim 10, Yamazaki et al. disclose: wherein at least one of the measurement values and the results of the comparison are stored (sections 0045-0049, 0051, 0054 and 0055).

Regarding claim 11, Yamazaki et al. disclose: wherein a reference of a run of at least one of the analysis process and a reference of at least a part of the analyzer is also stored (sections 0054 and 0055).

Regarding claim 12, Yamazaki et al. disclose: wherein at least one of the measurement values and the results of the comparison for a plurality of runs of the

analysis process are at least one of stored and statistically evaluated (sections 0045-0049, 0054, 0055, 0162 and 0163).

Regarding claim 13, Yamazaki et al. disclose: wherein at least one of the measurement values and the results of the comparison are stored in a third database (sections 0045-0049, 0054 and 0055).

Regarding claim 14, Yamazaki et al. disclose: wherein at least one the measurement values and the results of the comparison are used to at least one of assist maintenance of an analyzer for carrying out the analysis process and to provide feedback about a manufacturing processes of at least parts of the analyzer (sections 0045, 0047 and 0161-0163).

Regarding claim 15, Yamazaki et al. disclose: a device for carrying out the method as claimed in claim 1, said device comprising an analyzer for carrying out the analysis process (sections 0045, 0047 and 0161-0163).

Regarding claim 16, Yamazaki et al. disclose: wherein the device includes a computer workstation (sections 0047 and 0048).

Regarding claim 17, Yamazaki et al. disclose: wherein the computer workstation is connectable to the analyzer (sections 0047 and 0048).

Regarding claim 18, Yamazaki et al. disclose: wherein the analyzer and the computer workstation are connectable together via an electrically engineered data connection (sections 0047 and 0048).

Regarding claim 19, Yamazaki et al. disclose: wherein said first database is stored in the computer workstation (Fig. 1; sections 0003 and 0030).

Regarding claim 20, Yamazaki et al. disclose: wherein the computer workstation is designed for at least one of representing the part of the chain and for the statistical evaluation (sections 0043 and 0161-0163).

Regarding claim 21, Yamazaki et al. disclose: wherein at least one of a second database and at least parts of the third database are stored in the analyzer (sections 0045, 0047 and 0048).

Regarding claim 22, Yamazaki et al. disclose: wherein the analyzer is designed for determining the measurement values (sections 0045 and 0047).

Regarding claim 30, Yamazaki et al. disclose a device for performing an analysis process including a chain of sub-processes (Fig. 1; sections 0011 and 0012), the device comprising: means for storing at least one of fundamental chemical and physical basic sub-processes for the group in a first database (sections 0030-0035 and 0040); means for representing at least a part of the chain of the analysis process by specifying one of the basic sub-processes, per sub-processes of the part of the chain, using at least one control parameter and at least one associated threshold value (sections 0043 and 0161 ); means for determining measurement values of the control parameters for at least one run of the analysis process (sections 0162 and 0163); means for comparing the measurement values with the associated threshold values for the quality control (sections 0162 and 0163); and means for outputting a result of the comparing the measurement values with the associated threshold values for the quality control (section 0043).

Yamazaki et al. do not mention expressly: said comparison is in a chronological order of the occurrence of the sub-processes in the part of the chain in the course of the analysis process.

Ertel teaches a method for carrying out quality control for an analysis process including a chain of sub-processes (Abstract), including: comparing measurement values with associated threshold values for the quality control in a chronological order of the occurrence of the sub-processes in the part of the chain in the course of the analysis process (col. 5, lines 35-39; col. 11, lines 50-55; col. 15, lines 11-20; col. 26, lines 61-68; col. 30, lines 13-19; cols. 35-36, lines 50-8).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Yamazaki et al. by including the data comparison technique as taught by Ertel in order to in order to monitor the overall performance of the data quality control process and performance trends over time as well as conduct more detailed case-specific quality control surveillance (Ertel, Abstract and col. 35, lines 50-60).

Regarding claim 31, Yamazaki et al. disclose: wherein the device includes an analyzer (sections 0162 and 0163).

Regarding claim 32, Yamazaki et al. disclose: wherein the device includes a computer workstation (sections 0047 and 0048).

Regarding claim 33, Yamazaki et al. disclose: wherein the computer workstation is connectable to the analyzer (0047 and 0048).



Regarding claim 34, Yamazaki et al. disclose: wherein the analyzer and the computer workstation are connectable together via an electrically engineered data connection (0047 and 0048).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. in view of Ertel, as applied to claim 1 above, and further in view of Markham et al. (U.S. Pub. No. 20060149407).

Yamazaki et al. in view of Ertel teach the subject matter discussed above except: wherein a run of the analysis process is terminated if one of the measurement values violates a predetermined relation with respect to the associated threshold value during the comparison.

Markham et al. teach a quality management system, including: an analysis process (Abstract); and a run of the analysis process is terminated if one of the measurement values violates a predetermined relation with respect to an associated threshold value during the comparison (section 0228).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the teaching of Markham et al. in the combination of

Art Unit: 2863

Yamazaki et al. and Ertel in order to provide an event-based quality assurance system wherein process control is dynamically related to the quality assurance mechanism in real-time (Markham et al., Abstract).

4. Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. in view of Ertel, as applied to claims 1 and 15-18 above, and further in view of Berger et al. (U.S. Pub. No. 20010043882).

Regarding claims 23-26 and 29, Yamazaki et al. in view of Ertel teach the subject matter discussed above. Yamazaki et al. do not mention explicitly: wherein the analyzer includes a base unit and subunits, attachable into the base unit; wherein the subunits are provided with an electronic memory chip; wherein at least one of a second database and at least parts of the third database are stored in the subunits; wherein a reference of the respective subunit are stored in the third database; and wherein the analyzer includes a base unit and disposable, attachable into the base unit.

Berger et al. teach an analyzer for analyzing medical samples (Abstract), wherein the analyzer includes a base unit and subunits, attachable into the base unit (section 0016 and 0019); wherein the subunits are provided with an electronic memory chip (section 0019); wherein at least one of a second database and at least parts of a third database are stored in the subunits (section 0019); wherein a reference of the respective subunit are stored in the third database (section 0019); and wherein the analyzer includes a base unit and disposable, attachable into the base unit (section 0016 and 0019).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the teaching of Berger et al. in the combination of Yamazaki, et al. and Ertel in order to provide an analyzer in which different sensor modules can be exchanged by the user on-demand for various measurement purposes and wherein measurement data can be stored locally for later use (Berger et al., section 0016 and 0019).

Regarding claim 27, Yamazaki et al. in view of Ertel teach the subject matter discussed above except: wherein the analyzer is intended for analyzing at least one substance in a bodily fluid of a living being.

Berger et al. teach an analyzer for analyzing medical samples (Abstract), wherein

- the analyzer is intended for analyzing at least one substance in a bodily fluid of a living being (section 0031 ).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the teaching of Berger et al. in the combination of Yamazaki et al. and Ertel in order to provide an analyzer that can be used for analyzing medical samples, and preferably for analysis of body fluids, as an intended use of the claimed invention (Berger et al., section 0031).

Regarding claim 28, Yamazaki et al. in view of Ertel teach the subject matter discussed above except: wherein the analyzer and the computer workstation are connectable together via the Internet.

Berger et al. teach an analyzer for analyzing medical samples (Abstract), wherein the analyzer and the computer workstation are connectable together via the Internet (section 0018).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the teaching of Berger et al. in the combination of Yamazaki et al. and Ertel in order to provide an analyzer that can be used for analyzing medical samples in a location remote from a central unit (Berger et al., section 0031).

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

***Response to Arguments***

6. Applicant's arguments received 04/09/07 with respect to claims 1-8, 10-22, and 30-34 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1-8, 10-22, and 30-34 are rejected as new prior art reference (U. S. Pat. No. 5307262 to Ertel) has been found to teach the limitation argued by the Applicant. Detailed response is given in section 2 as set forth above in this Office action.

The rest of the Applicant's arguments regarding the dependent claims are reliant upon the issue discussed above, and are deemed to be non-persuasive as well for the reasons provided above.


***Contact Information***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiuqin Sun whose telephone number is (571)272-2280. The examiner can normally be reached on 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on (571)272-2269. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 2863

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

XS   
May 24, 2007

  
CAROL S.W. TSAI  
PRIMARY EXAMINER